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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,049	09/12/2003	Richard D. Cummings	7148.003	7472

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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,049	CUMMINGS ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,18 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,18 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/12/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 17-18 and 24-26 are pending.

Applicant's amendment of claims 17-18, cancellation of claims 6-15, 21-23, and addition of claims 24-26 as submitted in a communication filed on 7/21/2006 is acknowledged.

New claims 24-26 are deemed directed to the elected subject matter. Claims 17-18 and 24-26 are at issue and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

1. The specification was objected to due to the presence of non-capitalized trademarks and minor typographical errors. In view of Applicant's amendment to the specification, this objection is hereby withdrawn.

Claim Objections

2. Claims 6-14, 18 were objected to as being directed in part to non-elected inventions and due to the recitation of "50 °C. And which has core...chaperone activity". In view of Applicant's cancellation of claims 6-14 and amendment of claim 18, these objections are hereby withdrawn.

Claim Rejections - 35 USC § 101

3. Claims 6-7 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In view of Applicant's cancellation of claims 6-7, this rejection is hereby withdrawn.

Claim Rejections - 35 USC § 112, Second Paragraph

4. Claims 6-14 were rejected under 35 U.S.C. 112, second paragraph, for lack of antecedent basis. In view of Applicant's cancellation of claims 6-14, this rejection is hereby withdrawn.

Claim Rejections - 35 USC § 112, First Paragraph

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 17-18 remain rejected and new claims 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. This rejection has been discussed at length in the Non Final action mailed on 6/15/2006 and is maintained as it relates to claims 17-18 for the reasons of record and those set forth below. This rejection as it applies to new claims 24-26 is necessitated by amendment for the reasons set forth below.

8. Applicant argues that claims 17-18 have been amended to be directed to an expression system comprising a recombinant host cell comprising a first expressible polynucleotide which encodes a core 1 β 1,3-galactosyltransferase and a second expressible polynucleotide (i) having SEQ ID NO: 2, or (ii) that hybridizes under specific conditions to the polynucleotide of SEQ ID NO: 2.

9. Applicant's arguments have been fully considered but are not found persuasive. The Examiner acknowledges the amendments made to the claims. However, the claims still require a genus of nucleic acids having any structure wherein said nucleic acids encode core 1 β 1,3-galactosyltransferases, and a genus of nucleic acids encoding core 1 β 1,3-galactosyltransferase specific molecular chaperones, wherein said nucleic acids share structural features which do not constitute a substantial portion of the

genus. As previously stated in the Non Final action mailed on 6/15/2006, a sufficient written description of a genus of polynucleotides may be achieved by a recitation of a representative number of polynucleotides defined by their nucleotide sequence or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. However, in the instant case, the claims require a genus of nucleic acids which do not have any shared structural feature (those encoding any core1 β 1,3-galactosyltransferase), and a genus of nucleic acids which share a structural feature which does not constitute a substantial portion of the genus as the remainder of the structure of any nucleic acid encoding a chaperone of a core 1 β 1,3-galactosyltransferase is completely undefined and the specification does not define the remaining structural features necessary for members of the genus to be selected. It is noted that one of skill in the art would considered the recited hybridization conditions, particularly the wash conditions, to be low stringency conditions. This is also admitted by Applicant in the specification (paragraphs [143]-[145]). Thus, one of skill in the art would recognize that the genus of variants of the polynucleotide of SEQ ID NO: 2 recited in the claims would have a low percent sequence identity to SEQ ID NO: 2. It is reiterated herein that the art teaches how even small structural changes can lead to major changes in function. In the absence of a correlation between function and structure, or some knowledge/guidance as to the structural elements required in the recited nucleic acids such that they would encode proteins having the required activity, one cannot reasonably conclude that the structures disclosed in the specification are representative of the structures of all the nucleic acids required. Thus, for the reasons of record and those set forth above, the claimed invention is not deemed adequately described.

10. Claims 17-18 remain rejected and new claims 24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an expression system comprising an isolated recombinant host cell comprising a polynucleotide encoding the polypeptide of SEQ ID NO: 1

and a polynucleotide encoding the human core 1 β 1,3-galactosyltransferase as described in pages 50-54 of the specification, does not reasonably provide enablement for an expression system comprising a non-isolated host cell, wherein said host cell comprises (1) a nucleic acid which encodes any core 1 β 1,3-galactosyltransferase, and (2) a nucleic acid which hybridizes under the conditions recited to the polynucleotide of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

11. This rejection has been discussed at length in the Non Final action mailed on 6/15/2006 and is maintained as it relates to claims 17-18 for the reasons of record and those set forth below. This rejection as it applies to new claims 24-26 is necessitated by amendment for the reasons set forth below.

12. Applicant argues that claims 17-18 have been amended to be directed to an expression system comprising a recombinant host cell comprising a first expressible polynucleotide which encodes a core 1 β 1,3-galactosyltransferase and a second expressible polynucleotide (i) having SEQ ID NO: 2, or (ii) that hybridizes under specific conditions to the polynucleotide of SEQ ID NO: 2.

13. Applicant's arguments have been fully considered but are not found persuasive. The Examiner acknowledges the amendments made to the claims. However, the claims still encompass (1) non-isolated host cells, (2) nucleic acids encoding any core 1 β 1,3-galactosyltransferase, and (3) nucleic acids encoding a core 1 β 1,3-galactosyltransferase specific molecular chaperone wherein said nucleic acids hybridize under the same low stringency hybridization conditions previously recited. As previously stated in the Non Final action mailed on 6/15/2006, the specification contemplates using the polynucleotides of the invention in gene therapy and possibly in the generation of transgenic animals (paragraphs [84], [97], [98]). Therefore, in its broadest reasonable interpretation, the cells as recited in the claims encompass not only isolated cells but also host cells within a transgenic multicellular organism. The enablement provided is not commensurate in scope with the claims due to the extremely

large number of transgenic multicellular organisms comprising the recited cells encompassed by the claims, which the specification fails to teach how to generate or how to use. Similarly, the specification provides no information as to how to deliver the recited polynucleotides to a human being such that expression of said polynucleotides would occur.

With regard to the genus of nucleic acids encoding core 1 β 1,3-galactosyltransferases required by the claims, it is reiterated herein that the enablement provided is not commensurate in scope with the claims due to the extremely large number of polynucleotides of unknown structure encompassed by the claims. In the absence of some knowledge or guidance as to a structure/function correlation, or some knowledge as to the structural elements required in any nucleic acid encoding a core 1 β 1,3-galactosyltransferase, one of skill in the art would have to test an infinite number of nucleic acids to determine which ones encode a protein with the desired characteristics.

With regard to the genus of nucleic acids hybridizing under the conditions recited in the claims and encoding core 1 β 1,3-galactosyltransferase specific molecular chaperones, it is noted that the recited conditions are those which are exemplified in the specification as low stringency conditions (paragraphs [143]-[145]). The conditions recited include wash conditions at low temperature (22 C) and low formamide concentrations (25%-35%). Using the well known equation of Meinkoth and Wahl (Current Protocols in Molecular Biology, Hybridization Analysis of DNA Blots, pages 2.10.8-2.10.11, 1993), Tm = 81.5 °C +16.6x$\log_{10}$[Na+] +0.41x(%GC) - .61x(%form) – 500/L, the corresponding Tm for the polynucleotide recited in claim 17(b) at 0.2xSSC at 22 °C is approximately 78.1 °C assuming a G+C content of 50% (78.1 °C = 81.5 + 16.6x$\log_{10}$[3.9/100] +0.41x(%50) - 500/957 (L= 957 nucleotides; for 20xSSC the molar concentration of Na+ is 3.9). As known in the art, Tm is reduced by approximately 1 °C for each 1% mismatching, therefore under the conditions recited (0.2xSSC and 22 °C), a wash at 22 °C is equivalent to approximately 56.1% mismatching (56.1% = 78.1°C – 22°C). This level of mismatching amounts to 538 nucleotides which can be modified (538 = 0.561x957) within SEQ ID NO: 2. Thus,

while the genus of polynucleotides recited can potentially encompass variants of the polynucleotide of SEQ ID NO: 2 where more than half their structure is unknown, the specification is completely silent with regard to (1) a structure/function correlation which would enable one of skill in the art to determine which additional structural elements are required for a nucleic acid as recited to encode a protein with the desired activity, and/or (2) some guidance as to which are the structural elements required in any variant of the polynucleotide of SEQ ID NO: 2 which are associated with the recited activity, such that a reasonable number of species within the extremely large genus encompassed by the claims can be selected for testing.

With regard to claims 25-26, it is noted that while the claim requires the host cell to have the ability to perform post-translational glycosylation to form a core 1 structure, the specification fails to disclose the structural elements required in a core 1 β 1,3-galactosyltransferase specific molecular chaperone encoded by the recited nucleic acids such that said chaperone can assist in the folding/stability of any core 1 β 1,3-galactosyltransferase. It is not expected that all core 1 β 1,3-galactosyltransferases would have the same chaperones. Thus, in addition to determine which nucleic acids encode core 1 β 1,3-galactosyltransferases, and which of the variants of the polynucleotide of SEQ ID NO: 2 recited in the claims encode core 1 β 1,3-galactosyltransferase specific molecular chaperones, one of skill in the art would have to go through the burden of undue experimentation to identify which core 1 β 1,3-galactosyltransferases are associated with the chaperones encoded by the recited nucleic acids. Thus, for the reasons of record and those set forth above, one of skill in the art cannot reasonably conclude that the full scope of the claimed invention is enabled by the teachings of the specification or the prior art.

Claim Rejections - 35 USC § 102

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15. Claims 6-10, 13-14, 21, 23 were rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (WO 00/15796 published on March 23, 2000). In view of Applicant's cancellation of the instant claims, this rejection is hereby withdrawn.

16. Claims 17-18 and new claim 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (WO 00/15796 published on March 23, 2000). This a new rejection not previously introduced.

Claims 17-18 are directed in part to an expression system comprising a recombinant host cell comprising (1) a polynucleotide which can be expressed in said host cell, wherein said polynucleotide encodes a core 1 β3-galactosyl transferase, and (2) a polynucleotide which can be expressed in said host cell, wherein said polynucleotide comprises SEQ ID NO: 1. Claim 24 is directed to the expression system of claim 17 with the added limitation that both polynucleotides are operatively associated with an expression control sequence.

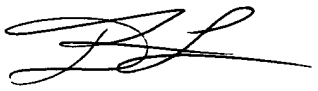
Chen et al. teach a human polypeptide which is identical to the polypeptide of SEQ ID NO: 1 (318 amino acids; PRO310; SEQ ID NO: 341; Figure 120) as well as its cDNA (1572 base pairs; SEQ ID NO: 340; page 55, lines 10-25; Figure 119). The cDNA of Chen et al. comprises all of SEQ ID NO:1. See attached alignments provided in the previous Office action. Chen et al. also teach an expression system comprising 293 host cells transformed with the polynucleotide of SEQ ID NO: 1 operatively linked to expression control elements such that it can be expressed in said cells (page 100, line 26). 293 host cells would also express a polynucleotide encoding the human core 1 β3-galactosyl transferase, as evidenced by the specification (page 51, lines 4-5) which discloses that the human core 1 β3-galactosyl transferase is endogenously produced by 293 cells. As such, the 293 cells of Chen et al. would also comprise a polynucleotide which encodes a core 1 β 3-galactosyl transferase that is expressed in said cells. Since the 293 cells of Chen et al. comprise a gene encoding a core 1 β 3-galactosyl transferase which is expressed in said cells, that gene would comprise expression control sequences. Thus, the teachings of Chen et al. anticipate the instant claims as written.

Conclusion

17. No claim is in condition for allowance.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
October 4, 2006